

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 9/00	A2	(11) International Publication Number: WO 99/38470 (43) International Publication Date: 5 August 1999 (05.08.99)
(21) International Application Number: PCT/US99/02010 (22) International Filing Date: 29 January 1999 (29.01.99) (30) Priority Data: 09/015,759 29 January 1998 (29.01.98) US (71)(72) Applicant and Inventor: SOLTANPOUR, David, Pyam [US/US]; 19A Addison Street, Larchmont, NY 10538 (US). (74) Agent: HOYTE, Alfred, F., Jr.; 131 E. Broad Street #206, Falls Church, VA 22046 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: METHOD AND APPARATUS FOR CONTROLLING INTRAOCULAR PRESSURE		
(57) Abstract		
<p>The present invention comprises a miniature pump which can be implanted in the eye for controllably removing excess fluid from the eye to treat glaucoma. The pump, in accordance with the inventive method, may be placed beneath the conjunctiva and/or extraocular muscles. In order to ensure that the right amount of fluid is removed from the eye the pump has a variable pumping rate, which results in a variable rate of removal of fluid from the eye. The pumping rate can be manually adjusted or automatically controlled in response to sensed ocular pressure. In the automatic mode, serious complications such as hypotony are avoided by reducing fluid flow when ocular pressure is low.</p> <div data-bbox="699 1136 1365 1545" data-label="Image"> </div>		

**METHOD AND APPARATUS FOR CONTROLLING INTRAOCULAR
PRESSURE**

BACKGROUND OF THE INVENTION

5 **1. FIELD OF THE INVENTION**

The present invention relates to controlling ocular pressure. More specifically, it relates to an improved method and apparatus for controlling glaucoma.

DESCRIPTION OF THE PRIOR ART

10 As will be seen, the simplicity and effectiveness of my invention is not rivaled in the prior art.

United States Patent No. 5,370,607 issued to Memmen discloses a glaucoma implant device which has a tubular shunt for draining fluid from the eye. By contrast, the present invention contemplates a controllable pumping mechanism for draining fluid from the eye to treat glaucoma.

15 United States Patent No. 4,911,616 issued to Laumann, Jr. discloses a microminiature pump which may be used to administer medications in sensitive locations in the body such as the eye. The pump is programmable, but the application does not

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

disclose which aspects of the pump operation can be controlled. By contrast, the present invention contemplates a miniature pump and conduit assembly which may be used to control glaucoma by controllably pumping fluid from the eye in accordance with sensed pressure conditions within the eye.

5 United States Patent No. 5,062,841 issued to Siegel discloses an insulin pump which can be used to pump insulin directly into the bloodstream in response to blood glucose levels. By contrast, the present invention contemplates a miniature pump which can be implanted into the tissue surrounding the eye and can controllably reduce ocular pressure.

10 None of the above inventions and patents, taken either singly or in combination, is seen to describe the instant invention as claimed.

SUMMARY OF THE INVENTION

15 Briefly, the invention comprises a miniature pump which can be implanted in the eye for controllably removing excess fluid from the eye to treat glaucoma. The pump, in accordance with the inventive method, may be placed beneath the conjunctiva and/or extraocular muscles. In order to ensure that the right amount of fluid is removed from the eye the pump has a variable pumping rate, which results in a variable rate of removal of fluid from the eye. The pumping rate can be manually adjusted or automatically controlled in response to sensed ocular pressure. In the automatic mode, serious
20 complications such as hypotony are avoided by reducing fluid flow when ocular pressure

is low.

Accordingly, it is a principal object of the invention to provide a new and improved method and apparatus for controlling glaucoma.

5 It is a major object of this invention to provide an implantable pump assembly and associated method for controlling intraocular pressure.

It is another object of the invention to provide such a pump assembly having an automatically controlled pumping rate.

10 It is still another object of the invention to provide an improved, biologically implantable pump assembly having a pumping rate which is controllable in response to sensed local pressure conditions.

It is another object of the invention to provide an improved method and apparatus for controlling glaucoma including a micropump which is implanted into the anterior chamber of the eye.

15 It is yet another object of the invention to provide an improved, biologically implantable pump assembly having a draining tube which is relatively wide to disperse the outflow of fluid.

Finally, it is a general object of the invention to provide improved elements and

arrangements thereof in an apparatus for the purposes described which is dependable and fully effective in accomplishing its intended purposes.

These and other objects of the present invention will become readily apparent upon further review of the following specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Various other objects, features, and attendant advantages of the present invention will become more fully appreciated as the same becomes better understood when considered in conjunction with the accompanying drawings, in which like reference characters designate the same or similar parts throughout the several views, and wherein:

Fig. 1 is a top view of the pump assembly of the present invention.

Fig. 2 is a side elevational view of a human eye upon which the device of the present invention has been implanted.

Fig. 3 is a top sectional view of the pump of Fig. 1 detailing the electronics.

Fig. 4 is a close up elevational view of the implanted pump.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1-4, a pump assembly, generally indicated by the numeral 10, is shown implanted in accordance with the method of the present invention. The pump 10 must be sufficiently small to be implanted in the eye without causing undue discomfort to the patient, and yet be able to store enough energy to pump fluid for a relatively long time. There are a few commercially available miniature pumps which meet this general criteria. In the preferred embodiment a Wilson Greatbatch Ltd. Model P65007 solenoid pump is used as the pump 10. The literature associated with this pump is hereby incorporated by reference. The pump is preferably about 5-15 millimeters long.

Referring specifically to Figs. 1 and 3, the pump 10, has a main body 20, which is made from biocompatible titanium or other biocompatible, corrosion resistant metal. Preferably, all of the parts of the pump in contact with bodily fluid are made from biocompatible titanium or other biocompatible, corrosion resistance metals. Also, the fluid flow path should be hermetically isolated from the solenoid coil and from the exterior of the pump. Of course, all of the electronics and the power source (not shown) must be contained within a hermetically sealed housing. The power source may be a small battery designed for long life. The pump 10 is designed to be driven by discharging a small value capacitor (about $25\mu\text{F}$) across a solenoid coil (not shown), which reciprocally operates a fluid displacement member or members (not shown) such as a piston.

The fluid displacement member operates to draw fluid into an intake conduit 22, into and through the main body 20 of the pump 10, and out through a drainage conduit 24 which has a fan shaped discharge end 26 to disperse the effluent fluid. The fan shaped

end 26 helps to reduce the possibility of fibrosis. Accordingly, the possibility of occlusion of the drainage conduit 24 is reduced. Additionally, antifibroblastic agents may be applied after surgery to prevent fibrosis. It should be noted that the intake and drainage conduits 22, 24 must be of sufficient diameter to accommodate the required fluid flow. It can be readily appreciated that the constant fluid flow associated with the inventive method will help to keep the conduits free of blockage.

The pump 10 includes a check valve 28 at least at the intake 30 to allow for selectively limiting fluid flow. The rate of fluid flow is electronically controllable and is variable from 0 to about 10 μ l per minute. In order to effectively control the rate of fluid flow or pumping rate, a microprocessor 34 and associated input logic 36 are operatively connected to the pump 10.

In the preferred embodiment, an active pumping action is employed. In order to effect such action, a pressure sensing device 38 must be employed. The pressure sensing device 38 is preferably small relative to the main body 20 of the pump 10 and is operatively connected to the microprocessor 34 for sending signals thereto. The pressure sensor 38 must be sufficiently sensitive to detect changes on the order of 1mm Hg. Also, the pressure sensor 38 is preferably operated from the same power supply used to operate the pump. Thus, in accordance with the present invention, excessive ocular pressure is sensed, and the pump is activated at a rate which is determined by the sensed ocular pressure. One advantage of this method is that hypotony, due to excessive drainage of ocular fluid, is avoided, a common problem associated with prior art methods. To that end, if a pressure of less than 7mm Hg is sensed the pump 10 can be shut off. Alternatively, an external control mechanism (not shown) may be employed to manually

control pump operation, when, e.g., the attending physician determines that the drainage rate is excessive.

5 Placement of the pump 10 is illustrated in Figs. 2 and 4. The main body 20 of the pump 10 may be placed under the extraocular muscles of the eye. The intake conduit 22 is placed to draw fluid from the anterior chamber of the eye, with the drainage conduit 24 being placed to discharge aqueous into the subconjunctival space.

10 In operation, after implantation of the device using standard surgical procedures, the pump 10 and sensor 38 will work in combination to monitor and control the immediate post operative eye pressure. Alternatively, a manual pressure sensor may be used and the pumping rate may also be adjusted manually as required.

 It is to be understood that the provided illustrative examples are by no means exhaustive of the many possible uses for my invention.

15 From the foregoing description, one skilled in the art can easily ascertain the essential characteristics of this invention and, without departing from the spirit and scope thereof, can make various changes and modifications of the invention to adapt it to various usages and conditions.

 It is to be understood that the present invention is not limited to the sole embodiment described above, but encompasses any and all embodiments within the scope of the following claims:

CLAIMS

I claim:

1. A method of controlling glaucoma by implanting a device for draining aqueous humor out of the anterior chamber of the eye, the method comprising the steps of:

implanting a miniature pump in or proximate the anterior chamber of the eye, in the subconjunctival space of the eye and securing it to the sclera of the eye, said miniature pump having an intake conduit positioned within the anterior chamber and a discharge conduit positioned in the subconjunctival space for draining the aqueous humor;

said pump including control means associated therewith for controlling the pumping rate, said pumping rate being controlled in response to the sensed ocular pressure.

2. A device to be surgically implanted in the eye for treating glaucoma by draining aqueous humor out of the anterior chamber of the eye comprising:

a miniature pump assembly for pumping said fluid out of the anterior chamber, said pump assembly including control means for controlling pumping rate, an intake conduit positioned within the anterior chamber and a discharge conduit positioned in the subconjunctival space for draining the aqueous humor;

said control means capable of controlling the pumping rate to prevent excessive drainage of fluid from said anterior chamber.

3. The device of claim 2 wherein said discharge conduit has a first end for connection

to said pump and an opposing end positioned to drain the aqueous into the subconjunctival space, said opposing end having a fan shaped tip.

4. The device of claim 2 wherein said control means includes a pressure sensing means operatively connected to a microprocessor, where said microprocessor is connected to a drive means for controlling the rate of fluid flow in response to the local pressure.
5. The device of claim 2 wherein said pump is made of biocompatible titanium.
6. The device of claim 4 wherein said rate of fluid flow is variable depending on the sensed intraocular pressure.
7. The device of claim 4 wherein said drive means can be manually controlled.
8. The device of claim 4 wherein said pressure sensing means is external to the eye.

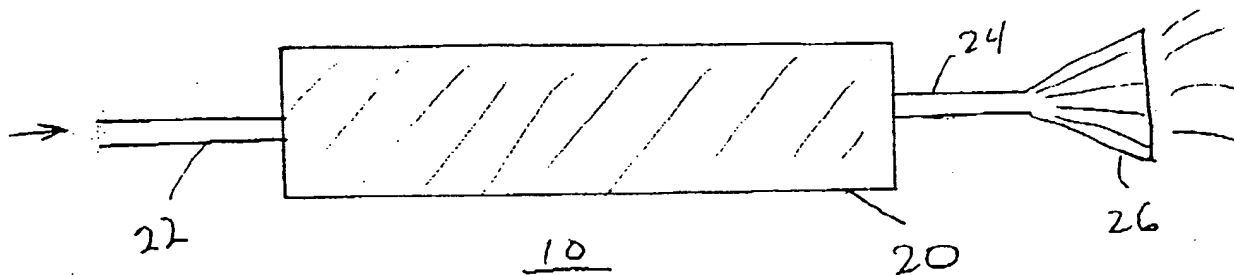


Fig. 1

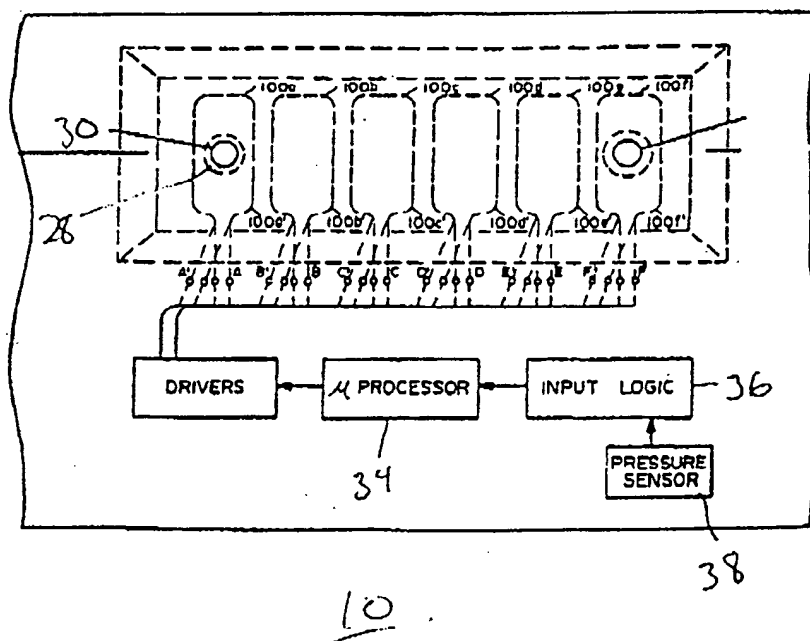
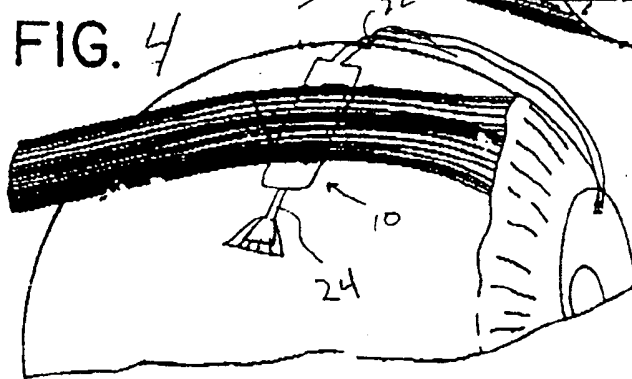
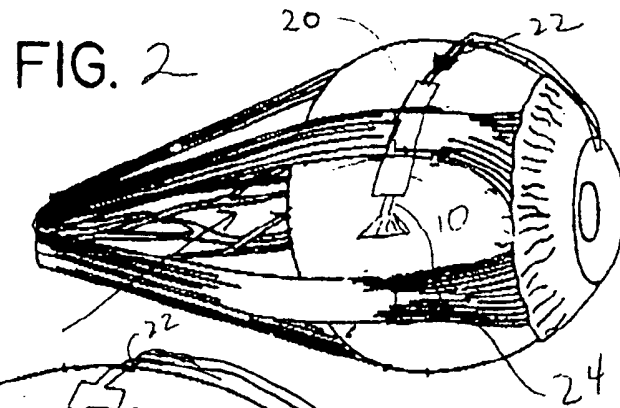
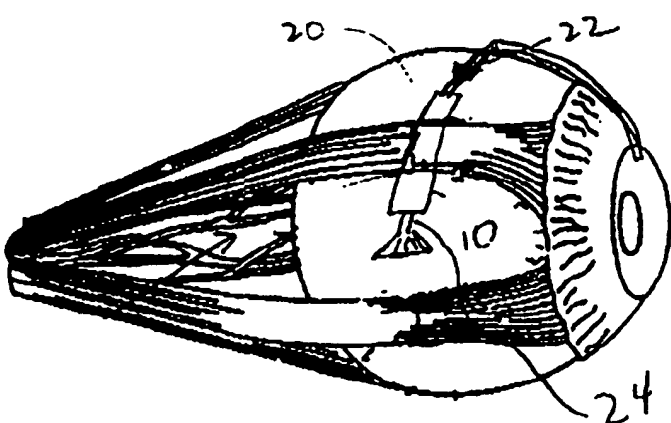


FIG. 3



PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 9/007	A3	(11) International Publication Number: WO 99/38470 (43) International Publication Date: 5 August 1999 (05.08.99)
(21) International Application Number: PCT/US99/02010 (22) International Filing Date: 29 January 1999 (29.01.99) (30) Priority Data: 09/015,759 29 January 1998 (29.01.98) US (71)(72) Applicant and Inventor: SOLTANPOUR, David, Pyam [US/US]; 19A Addison Street, Larchmont, NY 10538 (US). (74) Agent: HOYTE, Alfred, F., Jr.; 131 E. Broad Street #206, Falls Church, VA 22046 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> (88) Date of publication of the international search report: 7 October 1999 (07.10.99)
(54) Title: METHOD AND APPARATUS FOR CONTROLLING INTRAOCULAR PRESSURE (57) Abstract <p>The present invention comprises a miniature pump (10) which can be implanted in the eye for controllably removing excess fluid from the eye to treat glaucoma. The pump (10), in accordance with the inventive method, may be placed beneath the conjunctiva and/or extraocular muscles. In order to ensure that the right amount of fluid is removed from the eye the pump (10) has a variable pumping rate, which results in a variable rate of removal of fluid from the eye. The pumping rate can be manually adjusted or automatically controlled in response to sensed ocular pressure. In the automatic mode, serious complications such as hypotony are avoided by reducing fluid flow when ocular pressure is low.</p> 		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US 99/02010**

A. CLASSIFICATION OF SUBJECT MATTER <p style="margin-left: 40px;">A 61 F 9/007</p> <p style="font-size: small;">According to International Patent Classification (IPC) or to both national classification and IPC ⁶</p>		
B. FIELDS SEARCHED <p style="font-size: small;">Minimum documentation searched (classification system followed by classification symbols)</p> <p style="margin-left: 40px;">A 61 F, A 61 M</p> <p style="font-size: small;">Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched</p> <p style="font-size: small;">Electronic data base consulted during the international search (name of data base and, where practical, search terms used)</p>		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4911616 A (LAUMANN, C.W., JR.) 27 March 1990, fig. 7,8, abstract, column 7, line 60 - column 8, line 21, column 9, lines 14-27 (cited in the application). --	1, 2, 4
A	US 5370607 A (MEMMEN, J.E.) 06 December 1994, fig. 3-5, column 8, line 56 - column 9, line 24 (cited in the application). --	
A	WO 91/12046 A1 (ATOS MEDICAL AB) 22 August 1991, abstract, fig. 2, page 6,	5
<div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input type="checkbox"/> Patent family members are listed in annex. </div>		
<div style="display: flex;"> <div style="flex: 1;"> <p style="font-size: small;">* Special categories of cited documents:</p> <p style="font-size: x-small;">* A* document defining the general state of the art which is not considered to be of particular relevance</p> <p style="font-size: x-small;">* E* earlier document but published on or after the international filing date</p> <p style="font-size: x-small;">* L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p style="font-size: x-small;">* O* document referring to an oral disclosure, use, exhibition or other means</p> <p style="font-size: x-small;">* P* document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="flex: 1;"> <p style="font-size: x-small;">* T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p style="font-size: x-small;">* X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p style="font-size: x-small;">* Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p style="font-size: x-small;">* &* document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search <p style="text-align: center; margin-left: 40px;">23 July 1999</p>		Date of mailing of the international search report <p style="text-align: center; margin-left: 40px;">23. 08. 1999</p>
Name and mailing address of the ISA <p style="margin-left: 40px; font-size: x-small;">European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 631 epo nl, Fax (+ 31-70) 340-3016</p>		Authorized officer <p style="margin-left: 40px; margin-top: 10px;">LUDWIG e.h.</p>

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/02010

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>line 28 - page 7, line 9, claims 1,9,10. --</p> <p>US 5127901 A (ODRICH, R.B.) 07 July 1992, abstract, fig. 1-4, column 3, line 67 - column 4, line 46, column 5, lines 5-21. ----</p>	3

ANHANG

zum internationalen Recherchen-
bericht über die internationale
Patentanmeldung Nr.

ANNEX

to the International Search
Report to the International Patent
Application No.

ANNEXE

au rapport de recherche inter-
national relatif à la demande de brevet
international n°

PCT/US 99/02010 SAE 233913

In diesem Anhang sind die Mitglieder
der Patentfamilien der im obenge-
nannten internationalen Recherchenbericht
angeführten Patentdokumente angegeben.
Diese Angaben dienen nur zur Unter-
richtung und erfolgen ohne Gewähr.

This Annex lists the patent family
members relating to the patent documents
cited in the above-mentioned inter-
national search report. The Office is
in no way liable for these particulars
which are given merely for the purpose
of information.

La présente annexe indique les
membres de la famille de brevets
relatifs aux documents de brevets cités
dans le rapport de recherche inter-
national visée ci-dessus. Les renseigne-
ments fournis sont donnés à titre indica-
tif et n'engagent pas la responsabilité
de l'Office.

Im Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche		Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
US A	4911616	27-03-1990	keine - none - rien	
US A	5370607	06-12-1994	AU A1 62806/94 WO A1 9409837	24-05-1994 11-05-1994
WO A1	9112046	22-08-1991	EP A1 515489 SE A0 9000491 SE A 9000491	02-12-1992 12-02-1990 13-08-1991
US A	5127901	07-07-1992	US A 5041081	20-08-1991

THIS PAGE LEFT BLANK

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE LEFT BLANK